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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,300	08/29/2005	Jingwu Z Zang	050989.0201.01USPC	3842
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SUITE 1000 KANSAS CITY, MO 64112-1802			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
	10/524,300	ZANG, JINGWU Z			
Office Action Summary	Examiner	Art Unit			
	DiBrino Marianne	1644			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period v - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	lely filed the mailing date of this communication. (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on 24 M	action is non-final. nce except for formal matters, pro				
Disposition of Claims					
4) Claim(s) 31 and 33-42 is/are pending in the ap 4a) Of the above claim(s) 34-42 is/are withdraw 5) Claim(s) is/are allowed. 6) Claim(s) 31 is/are rejected. 7) Claim(s) 33 is/are objected to. 8) Claim(s) are subject to restriction and/or Application Papers 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acceeding a content of the drawing of the correct of the drawing sheet(s) including the correct	r election requirement. r. epted or b) objected to by the Edrawing(s) be held in abeyance. See	e 37 CFR 1.85(a).			
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 3/24/09.	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ite			

Application/Control Number: 10/524,300

Art Unit: 1644

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/24/09 has been entered.

Applicant's response filed 3/24/09 is acknowledged and has been entered.

2. Applicant is reminded of Applicant's election without traverse of Group III (claims 31-33), and species of SEQ ID NO: 1-6 in Applicant's responses filed 2/4/08 and 4/24/08, respectively.

Claims 31 and 33 read on the elected species and are currently being examined.

3. Applicant is reminded that the oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP 602.01 and 602.02.

The oath or declaration is defective because: Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

The Examiner notes that Applicant is seeking to obtain a supplemental declaration (page 2 of Applicant's response at #1b).

- 4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
 - A person shall be entitled to a patent unless -
 - (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 5. Claim 31 is rejected under 35 U.S.C. 102(b) as being anticipated by Correale *et al* (J. Neuroimmunol. 107: 130-139, 2000) as evidenced by an admission in the specification at Example 1, section 1, on pages 20-21.

Correale *et al* teach an autologous T cell vaccine comprising inactivated T cells against bovine myelin (see entire reference, especially abstract and section 2.3). Correale *et al* further teach that as there are differences between bovine and human myelin, and MBP, PLP and MOG are 90% homologous between human and bovine, they made peptides from each of these proteins that correspond to non-homologous regions between human and bovine. They found that there was no detectable proliferative

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response to any of the peptides that comprise the non-homologous human-bovine regions (especially section 3.1).

The admission in the specification at Example 1, section 1, on pages 20-21 is that SEQ ID NO: 1-6 correspond to known immunodominant regions of MBP, PLP and MOG.

Although Correale *et al* do not explicitly teach that the T cell vaccine comprises T cells that are reactive against SEQ ID NOS: 1-6 of the instant claim, Correale *et al* do teach that the proteins MBP, PLP and MOG of which SEQ ID NO: 1-2, 3-4 and 5-6, respectively, are subsequences, are included in the immunizing preparation for making the T cell vaccine, and the admission in the specification at Example 1, section 1 is that SEQ ID NO: 1-6 correspond to known immunodominant regions of these three myelin proteins. In addition, the instant claim recites "vaccine comprising inactivated T cells that are reactive against SEQ ID NOS: 1-6", *i.e.*, that the vaccine may comprise additional ingredients such as T cells of other specificities and that the T cells are reactive against, but not necessarily elicited by SEQ ID NOS: 1-6.

Therefore the claimed vaccine appears to be the same as the vaccine of the prior art absent a showing of differences. Since the Patent Office does not have the facilities for examining and comparing the composition of the instant invention to those of the prior art, the burden is on Applicant to show a distinction between the vaccine of the instant invention and that of the prior art. See <u>In re Best</u>, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

SEQ ID NO: 1 of the instant application is disclosed as "amino acids 110-126 of human myelin basic protein" [MBP] in the sequence listing, and SEQ ID NO: 2 of the instant application is disclosed as "amino acids 167 to 186 of human myelin basic protein".

However, Applicant's IDS reference Tejada-Simon *et al* (Eur. J. Immunol. 31: 907-917, 2001 that includes Jingwu Z. Zhang as an author) teach that a peptide identical to SEQ ID NO: 1 of the instant application is amino acid residues 83-99 of human MBP while a peptide that is identical to SEQ ID NO: 2 of the instant application is amino acid residues 151-170 of human MBP. This has bearing on the rejection set forth below.

Applicant is again requested to clarify this discrepancy.

7. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al (Science, 1993, 261: 1451-1454, Applicant's IDS reference filed 10/23/08) in view of Zhang (Crit. Rev. Immunol. 2001, 21: 41-55), Tejeda-Simon et al (International Immunol. 2000, 12(12): 1641-1650, Zhang is an author) and WO 97/35879 A1.

(Note that Applicant's argument in the response filed 3/24/09 concerning motivation to use the two specific MOG peptides taught by the WO 97/35879 A1 (Devaux) reference and cited in the prior 103(a) rejection of record over the combination of references applied herein has been found persuasive as it pertains to instant claim 33. Thus the said argument has overcome the prior rejection of record as it pertains to claim 33, wherein the vaccine *consists of* T cells that are reactive against SEQ ID NOS: 1-6, and claim 33 is not included in the instant rejection.)

Zhang *et al* teach that experimental autoimmune diseases can be treated by inoculation with autoreactive T cells (T cell vaccination), and that patients with MS were inoculated with irradiated (*i.e.*, inactivated) MBP-reactive T cells. Zhang *et al* further teach that T cell responses to the vaccine was induced to deplete circulating MBP-reactive T cells in the recipients. Zhang *et al* teach predominant reactivity to MBP peptides 84-102 and 143-168. Zhang *et al* do not depict the sequences of the peptides using single amino acid residue code (see entire reference).

Zhang *et al* differ from the claimed invention in that they don't *explicitly* teach that the vaccine comprises T cells that are reactive against SEQ ID NO: 1 and 2, nor that the vaccine further comprises, or in combination consists of, T cells that are reactive against SEQ ID NO: 3-6 in addition to SEQ ID NO: 1 and 2.

Zhang teaches that there are several myelin antigens implicated in MS, including MBP, PLP and MOG. Zhang further teaches that there is an immunodominant epitope between peptide residues 83-99 of human MBP, and that the T cell responses to MBP are focused on this region as well as on residues 151-170 during exacerbation and is shifted towards other epitopes of MBP at the time of remission. Zhang also teaches T cell vaccination with selected irradiated MBP-reactive T cell clones as a vaccine, resulting in a progressive decrease in the frequency or suppression of the circulating MBP-reactive T cells in an antigen-specific manner, and with reduced EDSS (Expanded Disability Status Score). Zhang does not teach which epitope(s) of MBP are being recognized by the administered T cells. Zhang teaches that it is important to incorporate most if not all candidate myelin antigens in the T cell vaccination protocol to test effectiveness (see entire reference).

Tejeda-Simon *et al* teach that a high precursor frequency of myelin-reactive T cells correlates with acute exacerbation in relapsing-remitting MS, correlating with reactivity to the immunodominant peptides of the candidate myelin antigens, predominantly BMP 150-170 in the majority of patients, and also MBP 83-99, PLP 30-49, PLP 180-199 and

MOG 41-60, as well as the Th1 cytokine profile at the time of exacerbation (see entire reference, especially abstract and discussion sections).

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WO 97/35879 A1 teaches MOG 20-mer peptides that are useful in compositions of the invention for treating MS, such as amino acid residues 1-20 and amino acid residues 21-40 (especially page 7 at Fig. 5 a legend, Figure 5a, claims) and in combination with other peptides from myelin antigens such as MBP and PLP (see entire reference, especially claims, including claims 21 and 25).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have included in the T cell vaccine taught by Zhang *et al*, T cells reactive with the MBP peptides taught by Zhang *et al* or those taught by Zhang (SEQ ID NO: 1 and 2 of the instant claims) plus T cells reactive with the PLP peptides taught by Tejeda-Simon *et al* and T cells reactive with the MOG peptides taught by WO 97/35879 A1, plus or minus T cells reactive with the MOG peptide taught by Tejeda-Simon *et al*.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to make a T cell vaccine that incorporates T cells that are reactive towards the immunodominant peptides from the MBP, PLP and MOG myelin proteins, particularly in light of the teaching of Zhang *et al* (2001) that it is important to incorporate most if not all candidate myelin antigens in a T cell vaccination protocol to test effectiveness, and the teaching of WO 97/35879 A1 to use MOG peptides in combination with other peptides from myelin antigens such as BMP and PLP in vaccines.

Although the PLP and MOG peptides are not SEQ ID NO: 3-4 and 5-6, respectively, of the instant claims, the instant claims recite that the T cell vaccine comprises "inactivated T cells that are reactive against SEQ ID NOS: 1-6, *i.e.*, that are reactive against, not elicited by, SEQ ID NOS: 1-6.

Zhang *et al* (1993) thus appear to implicitly teach an autologous T cell vaccine that consists of inactivated T cells that react with SEQ ID NO: 1 and 2 of the instant claims as SEQ ID NO: 1 is encompassed by MBP peptides 84-102 and SEQ ID NO: 2 is encompassed by to MBP peptide 143-168. PLP 30-49 taught by Tejeda-Simon *et al* is offset by one amino acid residue with respect to SEQ ID NO: 3 of the instant invention *i.e.*, amino acid residues 31-50 of PLP (as disclosed in the sequence listing), and PLP 180-199 is also offset by one amino acid residue with respect to SEQ ID NO: 4 of the instant invention, *i.e.*, amino acid residues 181-200 of PLP (as disclosed in the sequence listing). The MOG peptide 1-20 taught by WO 97/35879 A1 encompasses SEQ ID NO: 5 of the instant invention (amino acid residues 1-17), while the MOG peptide 20-40 overlaps SEQ ID NO: 6 of the instant invention (amino acid residues 18-38) by all but four amino acid residues. Zhang (2001) teaches SEQ ID NO: 1 and 2 of the instant claims are or contain important T cell epitopes in MS. It appears, absent evidence to the contrary, that the T cells in the vaccine of the combined references would be reactive against SEQ IS NO: 1-6 recited in the instant claims.

Therefore the claimed vaccine appears to be similar to the vaccine of the prior art absent a showing of unobvious differences. Since the Patent Office does not have the facilities for examining and comparing the composition of the instant invention to those of the prior art, the burden is on Applicant to show an unobvious distinction between the vaccine of the instant invention and that of the prior art. See <u>In re Best</u>, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Applicant's arguments have been fully considered but are not persuasive.

Applicant's said arguments are of record in the response filed 3/24/09 on pages 2-4, briefly that: (1) the simple substitution basis for obviousness requires a finding that the results of the substitution would have been predictable and consideration of the prior art references as a whole, (2) at the time the instant application was filed at least 123 peptides of MBP, 50 of PLP and 67 of MOG were known, and these are disclosed in the references cited in the instant rejection and in the IDS references currently submitted and in Appendices A-C, so there were at least 1.7 X 10⁷² possible different combinations of peptides from these three MS-associated peptides that could have been chosen, (3) the prior art gives no guidance to produce the instantly claimed T cell vaccine, (4) Zhang 1993 does not teach or suggest using any of the peptides having instant SEQ ID NO: 1-6, (5) Devaux (WO 97/35879 A1) does not teach or suggest making a T cell vaccine or using one to treat MS or provide motivation to make a T cell vaccine that is reactive to MOG peptides, but instead discloses using MOG peptides themselves as an immunoreactive treatment against MS, (6) OSA would not have the motivation or expectation of success for making the specific T cell vaccine of the instant claims which is reactive to two specific peptides each of MBP, PLP, and MOG from greater than 1.7 x 10⁷² unique combinations of peptides known at the time of filing the instant application, (7) Devaux does not teach or suggest using only the two specific MOG peptides to which the instantly claimed T cell vaccine is reactive, and if OSA were motivated to make a T cell vaccine using T cells reactive to immunodominant peptides, Devaux provides little guidance as to which, if any, MOG peptides to use, and (8) none of the cited references provides motivation or expectation of success to OSA for arriving at the T cell vaccine of claim 1 with specific reactivity to two particular peptides each of MBP, PLP and MOG from the infinite number of possible peptide combinations known in the art at the time of filing.

However, (1) and (2) The peptides found in Applicant's Appendices A-C and IDS filed 3/24/09 are not all taught by the art references cited herein. Zhang *et al* 1993 teach a peptide that comprises SEQ ID NO: 1 and another that comprises SEQ ID NO: 2 exclusive of amino acid residues 169 and 170 of SEQ ID NO: 2 and that these peptides account for predominant T cell reactivity to MBP. Zhang *et al* 2001 teach SEQ ID NO: 1 and SEQ ID NO: 2 and that these peptides contain immunodominant T cell epitopes in MS. Tejeda-Simon *et al* teach SEQ ID NO: 1, a peptide comprising SEQ ID NO: 2 and a correlation of T cell reactivity of MS patients with these peptides in acute exacerbation, as well as with a peptide that is SEQ ID NO: 3 and one that is SEQ ID

NO: 4 of the instant claims. In addition WO 97/35879 A1 teaches MOG peptides that may be important to include in vaccines to treat MS, including a peptide that comprises SEQ ID NO: 5 and one that overlaps SEQ ID NO: 6 by all but four amino acid residues. Thus, the art references do not encompass at least 1.7 X 10⁷² possible different combinations of peptides from these three MS-associated peptides that could have allegedly been chosen from references not cited herein, nor from Appendices A-C (i.e., the Appendices are bar graphs over the length of the respective proteins showing amino acid ranges for peptide segments of the three proteins, which are not evidence that these peptides are T cell epitopes for treatment of MS, as no documentation for these segments of the three proteins are provided, nor are the exact amino acid residue numbers), (3) the prior art references give guidance to produce the instantly claimed invention as enunciated supra, and the vaccine of claim 31 "comprises" T cells reactive, not elicited by, the recited SEQ ID NO: 1-6, (4) and (5) the references are being argued separately by Applicant, (6) this point has been addressed by the Examiner, (7) claims 21 and 25 of WO 97/35879 A1 provide guidance for using MOG 1-20 and MOG 21-40 in a composition, and the instant claim 31 recites "comprising" not "consisting of", and (8) Claim 31 is not limited to T cells reactive with only the recited SEQ ID NO, and the argument as to the number of peptide combinations has been addressed. Thus, the references have been considered as a whole, and for the reasons enunciated herein, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success in producing the claimed invention from the combination of references cited herein.

With regard to (4) and (5), in response to Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

8. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0091578 A1 (IDS reference filed 3/24/09, Zhang) in view of Zhang (Crit. Rev. Immunol. 2001, 21: 41-55, of record), Tejeda-Simon *et al* (International Immunol. 2000, 12(12): 1641-1650, Zhang is an author, of record) and WO 97/35879 A1.

US 2003/0091578 A1 discloses an autologous T cell vaccine for the treatment of MS, said vaccine comprising inactivated T cells reactive with antigens or fragment(s) of myelin antigens selected from the group consisting of MBP, PLP and MOG, including MBP 83-99 and MBP 151-170 (*i.e.*, SEQ ID NO: 1 and 2 of the instant claim 31) (see entire reference, especially abstract, [0003], [0004], [0009], [0033], claims 4, 11 and 16).

US 2003/0091578 A1 does not teach that the autologous T cell vaccine also comprises inactivated T cells that are reactive against SEQ ID NO 3-6 of instant claim 31.

Zhang teaches that there are several myelin antigens implicated in MS, including MBP, PLP and MOG. Zhang further teaches that there is an immunodominant epitope between peptide residues 83-99 of human MBP, and that the T cell responses to MBP are focused on this region as well as on residues 151-170 during exacerbation and is shifted towards other epitopes of MBP at the time of remission. Zhang also teaches T cell vaccination with selected irradiated MBP-reactive T cell clones as a vaccine, resulting in a progressive decrease in the frequency or suppression of the circulating MBP-reactive T cells in an antigen-specific manner, and with reduced EDSS (Expanded Disability Status Score). Zhang does not teach which epitope(s) of MBP are being recognized by the administered T cells. Zhang teaches that it is important to incorporate most if not all candidate myelin antigens in the T cell vaccination protocol to test effectiveness (see entire reference).

Tejeda-Simon *et al* teach that a high precursor frequency of myelin-reactive T cells correlates with acute exacerbation in relapsing-remitting MS, correlating with reactivity to the immunodominant peptides of the candidate myelin antigens, predominantly BMP 150-170 in the majority of patients, and also MBP 83-99, PLP 30-49, PLP 180-199 and MOG 41-60, as well as the Th1 cytokine profile at the time of exacerbation (see entire reference, especially abstract and discussion sections).

WO 97/35879 A1 teaches MOG 20-mer peptides that are useful in compositions of the invention for treating MS, such as amino acid residues 1-20 and amino acid residues 21-40 (especially page 7 at Fig. 5 a legend, Figure 5a, claims) and in combination with other peptides from myelin antigens such as MBP and PLP (see entire reference, especially claims, including claims 21 and 25).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have included in the T cell vaccine disclosed by US 2003/0091578 A1, including the T cells disclosed by US 2003/0091578 A1 that are reactive with the MBP peptides 83-99 and 151-170, the same peptides taught by Zhang (SEQ ID NO: 1 and 2 of the instant claims), plus T cells reactive with the PLP peptides taught by Tejeda-Simon *et al* and T cells reactive with the MOG peptides taught by WO 97/35879 A1, plus or minus T cells reactive with the MOG peptide taught by Tejeda-Simon *et al*.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to make a T cell vaccine that incorporates T cells that are reactive towards the immunodominant peptides from the MBP, PLP and MOG myelin proteins, particularly in light of the disclosure of US 2003/0091578 A1 and of Zhang *et al* (2001) that it is important to incorporate T cells or T cell candidate myelin antigens in a T cell vaccination protocol to test effectiveness, and the disclosure of US 2003/0091578 A1 and the teaching of WO 97/35879 A1 to use MOG peptides in combination with other peptides from myelin antigens such as BMP and PLP in vaccines.

Although the PLP and MOG art peptides are not SEQ ID NO: 3-4 and 5-6, respectively, of the instant claims, the instant claims recite that the T cell vaccine comprises inactivated T cells that are reactive against SEQ ID NOS: 1-6, *i.e.*, that are reactive against, not elicited by, SEQ ID NOS: 1-6.

PLP 30-49 taught by Tejeda-Simon *et al* is offset by one amino acid residue with respect to SEQ ID NO: 3 of the instant invention *i.e.*, amino acid residues 31-50 of PLP (as disclosed in the sequence listing), and PLP 180-199 is also offset by one amino acid residue with respect to SEQ ID NO: 4 of the instant invention, *i.e.*, amino acid residues 181-200 of PLP (as disclosed in the sequence listing). The MOG peptide 1-20 taught by WO 97/35879 A1 encompasses SEQ ID NO: 5 of the instant invention (amino acid residues 1-17), while the MOG peptide 20-40 overlaps SEQ ID NO: 6 of the instant invention (18-38) by all but four amino acid residues. Thus, it appears, absent evidence to the contrary, that the T cells in the vaccine of the combined references would be reactive against SEQ IS NO: 1-6 recited in the instant claims.

Therefore the claimed vaccine appears to be similar to the vaccine of the prior art absent a showing of unobvious differences. Since the Patent Office does not have the facilities for examining and comparing the composition of the instant invention to those of the prior art, the burden is on Applicant to show an unobvious distinction between the vaccine of the instant invention and that of the prior art. See <u>In re Best</u>, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

With regard to Applicant's arguments to the prior rejection of record under 35 USC 103(a), the Examiner's comments to Applicant's arguments as they apply to the references applied herein, also apply herein as enunciated supra.

- 9. Claim 33 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- 10. Applicant is reminded of the following. With regard to Applicant's letter filed 2/4/05 regarding the inventor's name, it is unclear if the difference in the spelling of the inventor's name in the present application versus in the priority documents is the result of a clerical error, *i.e.*, Jingwu Z. Zang in the instant application versus Jingwu Z. Zhang in the priority documents. Although 37 CFR 1.48(f) will act to automatically correct an earlier identification of inventorship in a nonprovisional application by the filing of an initial executed oath or declaration, 37 CFR 1.48(f) is not applicable for national stage applications filed under 35 U.S.C. 371 where the inventorship has been erroneously named in the international application. Accordingly, if the inventorship set forth in the oath or declaration filed in the national stage application differs from the inventorship specified in the international application, the requirements of 37 CFR 1.497(d) must be satisfied. See MPEP 1893.01(e). Applicant is reminded that if Applicant intends to change inventorship, such change is a petitionable matter.

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11. No claim is allowed.

- 12. With regard to Applicant's Forms 1449 filed 3/24/09, the following applies:
 - Reference B4 was not considered by the Examiner because it was not provided in its entirety.
 - References B3C1-C3, C36, C57, C58 and C59-C62 have not been considered by the Examiner because they can not be located or Applicant has not provided copies.
 - Reference C71 was not considered by the Examiner because it is not in the English language and no explanation of relevance has been provided.
- 13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ram Shukla, can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marianne DiBrino, Ph.D. Patent Examiner Group 1640 Technology Center 1600 May 14, 2009

/G.R. Ewoldt/ Primary Examiner, Art Unit 1644